



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

**SEP 23 2015**

Hewet Iskandar, CNMT  
Radiation Safety Officer  
South County P.E.T. Imaging  
10010 Kennerly Road  
St. Louis, MO 63128

Dear Mr. Iskandar:

This refers to the letter dated June 23, 2015, signed by Dr. James Monroe as RSO for St. Anthony's Medical Center; Dr. Eric Applegren as Vice President of Clinical Operations for St. Anthony's Medical Center; and Dr. T. Martin Vollmar, as Administrator for South County P.E.T. Imaging. This letter described a change of ownership and control transaction that occurred on July 1, 2015.

This letter describes the transaction as St. Anthony's Medical Center's acquisition of the assets and operations of South County P.E.T. Imaging.

Our review has concluded that this transaction resulted in a change of ownership and control for South County P.E.T. Imaging and that the transaction has not resulted in any changes that affect the license or licensed program.

Your letter has been reviewed by our staff. We have concluded that South County P.E.T. Imaging has experienced a change of ownership and control involving NRC-regulated materials under your License No. 24-32731-01.

NRC hereby consents to the change of ownership transaction as described in your letter dated June 23, 2015, signed by Dr. James Monroe as RSO for St. Anthony's Medical Center; Dr. Eric Applegren as Vice President of Clinical Operations for St. Anthony's Medical Center; and Dr. T. Martin Vollmar, as Administrator for South County P.E.T. Imaging.

Only the last condition of your license has changed in relation to your licensed program so Amendment No. 02 is enclosed.

We appreciate the opportunity to review the description of your change of control letters with respect to compliance with 10 CFR 30.35 (b)(4).

Please note that, despite references made in your letter that appear to indicate that St. Anthony's Medical Center has now incorporated your licensed program into its own, this is not the case. In order for that to happen, you must request termination of your NRC license concurrent with the merger of your licensed program and facilities into the NRC license for St. Anthony's Medical Center.

And, St. Anthony's Medical Center must submit a separate amendment request to merge your licensed program and facilities into its NRC license concurrent with the termination of your NRC

license.

Please submit amendment requests for these changes by preparing written business letters, addressed to my attention at the above address, as "additional information to control number 587203."

It is especially important that these requests be in writing, currently dated, contain the authorized signature of an appropriate management representative, and also have enclosed sufficient supporting information to complete our review of them.

Your request for termination should be fairly simple and an NRC Form 314, available on our website, may be added to your request.

The amendment request to add your licensed program and personnel into the license for St. Anthony's Medical Center will be slightly more involved, as more information will be required.

Please arrange to call me to discuss the information needed so as to ensure that a high quality amendment application is prepared for this purpose.

If you have any questions concerning these matters please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of the enclosed license amendment, Safety Evaluation Report (SER) and this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

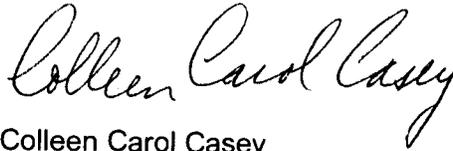
The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

H. Iskandar

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We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 24-32731-01  
Docket No. 030-37894

Enclosures:

1. Amendment No. 02
2. SER dated September 23, 2015

**SAFETY EVALUATION REPORT  
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER  
24-32731-01, SOUTH COUNTY P.E.T. IMAGING**

**DATE:** September 23, 2015

**DOCKET NO.:** 030-37894

**LICENSE NO.:** 21-32731-01

**LICENSEE:** South County P.E.T. Imaging  
10010 Kennerly Road  
St. Louis, MO 63128

**TECHNICAL REVIEWER:** Colleen Carol Casey

**SUMMARY AND CONCLUSIONS**

South County P.E.T. Imaging is authorized by NRC License 24-32731-01 for the possession and use of byproduct material for purposes of diagnostic uses in humans in unsealed forms. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by South County P.E.T. Imaging that resulted from the acquisition of the assets and operations of South County P.E.T. Imaging by St. Anthony's Medical Center on July 1, 2015. The licensee's request dated June 23, 2015, did not explicitly identify their letter as a request for "a direct transfer of control" but NRC staff considered that the request implicitly constituted as much.

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession ML15176A339.

The licensees' letter dated June 23, 2015, signed by appropriate management representatives for both parties, requested NRC's consent to the change in control. This letter also contained information pertaining to changes to the affected licenses as though St. Anthony's Medical Center would be incorporating South County P.E.T. Imaging's licensed activities into its own NRC license, which was excluded from the review. The exclusions are noted in Condition No. 14.C.

In the cover letter transmitting the NRC's consent to the change in ownership, the affected licensees were advised to submit these changes under separate cover as amendment requests to their licenses. The first step in transitioning the South County P.E.T. Imaging program into the license for St. Anthony's Medical Center was the change of ownership and is concluded. Now the remaining steps to terminate the NRC license for South County P.E.T. Imaging concurrent with its merger into the NRC license for St. Anthony's Medical Center may commence by the submission of appropriate amendment requests for each licensee.

The letter dated June 23, 2015, was reviewed by NRC staff and considered to constitute a request for consent to direct changes in control of a 10 CFR Part 30 license, using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000. The NRC staff finds that the information

submitted by South County P.E.T. Imaging sufficiently describes and documents the transaction and commitments made by South County P.E.T. Imaging and St. Anthony's Medical Center.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the letter dated June 23, 2015, and finds that the change in control was in accordance with the Act. The staff finds that South County P.E.T. Imaging remains qualified to use byproduct material for the purposes requested, and continues to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the security of licensed material.

## **SAFETY AND SECURITY REVIEW**

According to data obtained from the NRC's Licensing Tracking System (LTS), South County P.E.T. Imaging has been an NRC licensee since March 19, 2009. The NRC conducted an inspection of South County P.E.T. Imaging on March 3, 2014, and no violations were identified during this inspection. The commitments made by South County P.E.T. Imaging and St. Anthony's Medical Center state that South County P.E.T. Imaging License No. 24-32731-01:

- A. has not changed the radiation safety officer listed in the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license;
- E. has not changed the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

As a result of this transaction, St. Anthony's Medical Center owns and operates this facility. Therefore, for security purposes, St. Anthony's Medical Center is considered a known entity, following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," September 3, 2008, revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants, or NRC licensees transferring control of licensed activities, that the licensed material will be used for its intended purpose and not for malevolent use.

South County P.E.T. Imaging is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 24-32731-01.

## **REGULATORY FRAMEWORK**

South County P.E.T. Imaging's License No. 24-32731-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the change in control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15. As discussed in NUREG-I 556, Volume 15, NRC is generally using the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed.

The South County P.E.T. Imaging request for consent describes a direct change of control resulting from the asset and operations acquisition of South County P.E.T. Imaging by St. Anthony's Medical Center, as the new owner for South County P.E.T. Imaging. As the completion of the transaction took place on July 1, 2015, South County P.E.T. Imaging directly became owned by St. Anthony's Medical Center and, as such, the transfer required NRC consent.

#### **DESCRIPTION OF TRANSACTION**

The transaction is described in ADAMS accession number ML15176A339. Since the transaction date of July 1, 2015, St. Anthony's Medical Center has continued as the licensee and remains in control of all licensed activities under Materials License No. 24-32731-01. The NRC staff finds that the request for consent adequately provides complete and clear descriptions of the transaction, and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15.

#### **TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS**

The NRC staff finds that the information submitted by South County P.E.T. Imaging sufficiently describes and documents the commitments made by South County P.E.T. Imaging and St. Anthony's Medical Center and is consistent with the guidance in NUREG-1556, Volume 15.

#### **ENVIRONMENTAL REVIEW**

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(xi).

#### **CONCLUSION**

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 24-32731-01 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the licensee and commitments; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they have and will maintain the existing records; and, in the future, will abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15.

Therefore, the staff concludes that the proposed change in control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.